

# **ClinicalTrials.gov Registration User's Guide**

**For questions please contact  
[UHResearchCompliance@UHhospitals.org](mailto:UHResearchCompliance@UHhospitals.org)**

CT ClinicalTrials.gov PRS: Login x +

← → ↻ 🏠 CT https://register.clinicaltrials.gov

My Access | Employ... CT ClinicalTrials.gov-Pu... CT ClinicalTrials.gov Pr... eCFR :: 42 CFR Part... For Employees | Uni... Clinical Research &... Airwa

Use this address to enter registration information

# ClinicalTrials.gov PRS

Protocol Registration and Results System

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

To request a new account or reset your password, email [UHResearchCompliance@UHhospitals.org](mailto:UHResearchCompliance@UHhospitals.org)

Organization is case sensitive and site specific so make sure you use UHClevelandMC

Organization:   
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:  [Forgot password](#)

Username is first initial/last name

CT.gov will email a generated password, you will be prompted to change it the first time logging in

# Help

*ClinicalTrials.gov PRS*  
Protocol Registration and Results System

Quick Links

[New Record](#)

Records ▾

Accounts ▾

Help ▾

- From the Help menu choose “Protocol Data Entry”
- The PRS Guided Tutorials are helpful in providing examples

Help: Protocol Data Entry

Need help understanding protocol data entry? For introductory information on the process, see the [PRS Guided Tutorials](#).

Additional resources for protocol registration:

- [Protocol Registration Data Element Definitions](#) - describes the registration data items (required and optional) that are entered via PRS
- Protocol Registration Templates: Each template is a formatted summary of the data elements for each registration module, specific to the relevant study type. The templates are intended to help investigators understand and gather the data needed to complete each registration module.
  - [Interventional Study Protocol Registration Template \(PDF\)](#)
  - [Observational Study Protocol Registration Template \(PDF\)](#)
  - [Expanded Access Protocol Registration Template \(PDF\)](#)
- [Expanded Access Data Element Definitions](#) - describes the expanded access data items (required and optional) that are entered via PRS
- [Protocol Review Criteria \(PDF\)](#) - review criteria for submitted study records
- [Frequently Asked Questions \(FAQ\)](#)

U.S. Laws: Clinical trial registration and results submission

- [Final Rule for Clinical Trials Registration and Results Information Submission \(42 CFR Part 11\)](#) - clarifies and expands requirements for submitting clinical trial registration and results information to ClinicalTrials.gov in accordance with Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801)
- [FDAAA 801 Requirements](#) - clinical trial registration and results submission requirements from Section 801 of the Food and Drug Administration (FDA) Amendments Act of 2007
- [FDAMA 113 Requirements](#) - clinical trial registration requirements under Section 113 of the Food and Drug Administration Modernization Act of 1997

# Getting Started.....

- Link to SOPs for ClinicalTrials.gov:
  - <https://www.uhhospitals.org/-/media/Files/For-Clinicians/Research/clinical-research-sop-manual.pdf?la=en&hash=90B17F1B80AA9FCD754ED989B53222F557613696>
- If you would like to set up a one on one to walk through the registration please email [UHResearchCompliance@UHhospitals.org](mailto:UHResearchCompliance@UHhospitals.org)
- Registration can take ~2 hours to complete
- Can be saved as a draft and finished later. Make sure to always hit the “Save” button on the bottom of each page



- Once you have entered all the required data, hit the green “Entry Complete” button, it will then go to the Responsible Party to be Approved and Released, then to ClinicalTrials.gov for PRS review (can take up to a week)
- After CT.gov reviews, the record owner will get an email with the NCT# or with PRS comments, which should be addressed within **15 calendar day**
- Records are required to be updated annually, or more frequently as changes occur
  - Each time you are in the record make sure to update the Record Verification to current month/year

To create a new record, click the New Record link or use the Records drop down menu

To try out the new PRS system click here. PRS will switch over in 2023

Quick Links  
[New Record](#)  
[Quick Start Guide](#)  
[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Email: [Rachael.Massey@UHhospitals.org](mailto:Rachael.Massey@UHhospitals.org) [[Update](#)]

To edit an existing record click on the Open link

Try out the new PRS beta home page, part of the ongoing ClinicalTrials.gov modernization.

[New PRS Beta Home Page](#)

The system flags records with problems that need to be fixed

Record List

Showing: 1 record

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Responsible Party	Problems
<a href="#">Open</a>	1258 RM Test		Muscle O2 Saturation	In Progress	04/26/2022 10:25	Rachael Massey <a href="mailto:Rachael.Massey@UHhospitals.org">Rachael.Massey@UHhospitals.org</a>	<ul style="list-style-type: none"><li>• Entry Not Completed</li><li>• Never Released</li></ul>

The Record Owner defaults to who starts the record and is the primary contact for ClinicalTrials.gov. If you need to change the Record Owner please email: [UHResearchCompliance@UHhospitals.org](mailto:UHResearchCompliance@UHhospitals.org)

## Record Summary Page

Add anyone who needs edit rights.  
Record Owner can do this.

*In Progress* → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Confirm data entry complete

Entry Complete

Record Owner: RMassey

Last Update: 04/28/2022 10:20 by RMassey

Initial Release: [Not yet released]

Access List:  [Edit](#)

Upload: Allowed [Edit](#)

PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDAAA: ACT

**Initial Release** date displays on the public site. This is important for ACTs and ICMJE

Click **Entry Complete** once all edits are complete. This will send the record to the Responsible Party for Approval and Release

# Record Summary

[Spelling](#)

[Preview](#)

[Draft Record](#)

Click the **Spelling** link to review spelling errors

[Open](#)

## Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: STUDY20221234 RM

Brief Title: Remuverol in Adults With Disc Herniation

Module Status:

Study Identification: ✓

Study Status: **1 Error** [1 Note](#)

Sponsor/Collaborators: ✓

Oversight: **1 Warning**

Study Description: ✓

Conditions: ✓

Study Design: ✓

Arms and Interventions: ✓ **3 Notes**

Outcome Measures: ✓

Eligibility: ✓

Contacts/Locations: **Information is required**

IPD Sharing Statement:

References:

Click the **Open** link to make edits to the different sections of the record

**Error:** must be addressed before submitting the record

**Warning:** not required to be addressed, but should try and address if possible

**Note:** potential issues, should be reviewed and addressed as needed

[Help](#) [Definitions](#)

Each screen has a Help and Definitions link for further information on that section

\* Organization's Unique Protocol ID:

\* Brief Title:

[Special Characters](#)

Use the IRB assigned number

[\*] Acronym:  
(if any)

If specified, will be included at end of Brief Title in parentheses.

Click Continue to save progress and navigate to the next screen

\* Study Type:

- Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational** participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

Continue

Cancel

\* Required  
\* § Required if Study Start Date is on or after January 18, 2017  
[\*] Conditionally required (see Definitions)

Make sure to include all required information



Once you enter the brief title and study type this page will display. It is letting you know the different sections of the record. Hit **OK** after you review.

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Arms and Interventions
- Outcome Measures
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.



[Help](#) [Definitions](#)

\* Organization's Unique Protocol ID:

This title will be displayed in search results

\* Brief Title:

[\*] Acronym:   
If specified, will be included at end of Brief Title in parentheses.

Needs to match title submitted to IRB

\* § Official Title:

For NIH funded studies, add the Grant Number. If you get an error, leave blank and try adding later. It can take a few weeks for numbers to show in the system

[\*] Secondary IDs:

\* Required

\* § Required if Study Start Date is on or after January 18, 2017

# Study Status

\* Record Verification Date:

Month: April ▼ Year: 2022

Update RVD **every time** the record is updated. Records are required to be verified annually, this is how they track.

\* Overall Recruitment Status:

Not yet recruiting ▼

Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Only use “Active, not recruiting” if data is still being collected. If data collection is complete, the status should be Completed or Terminated.

## Overall Recruitment Status \*

Definition: The recruitment status for the clinical study as a whole, based upon the status of the individual sites. If **at least one** facility in a multi-site clinical study has an Individual Site Status of “Recruiting”, then the Overall Recruitment Status for the study must be “Recruiting”. Select one:

- **Not yet recruiting:** Participants are not being recruited
- **Recruiting:** Participants are currently being recruited, whether or not any participants have yet been enrolled
- **Enrolling by invitation:** Participants are being (or will be) selected from a predetermined population
- **Active, not recruiting:** Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
- **Completed:** The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant’s last visit has occurred)
- **Suspended:** Study halted prematurely but potentially will resume
- **Terminated:** Study halted prematurely and will not resume, participants are no longer being examined or receiving intervention
- **Withdrawn:** Study halted prematurely, prior to enrollment of first participant

# Study Start Date

Day is required for actual dates

Tip: Day is not required for Anticipated dates.

\* § Study Start Date:

Month:  Day:  Year:  Type:

Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

Study Start Date is either:  
**Anticipated**- estimated date which the study will be open for recruitment  
**Actual**- date of enrollment of first participant

# Primary and Study Completion Dates

\* Primary Completion Date: Month:  Day:  Year:  Type:   
**Final data collection date for primary outcome measure.**

\* § Study Completion Date: Month:  Day:  Year:  Type:   
**Final data collection date for study.**

**Completion Dates are based on data collection!  
They are NOT based on:**

- data analysis
- database lock
- publication
- IRB closure

Final data collection for the primary **and** secondary outcome measures **and** adverse events (for example, last participant's last visit)  
**Examples on next slide**

# Primary and Study Completion Dates

**Remember:** If required, results for the primary outcome measure(s) are due within one year of the Primary Completion Date. Results for the secondary outcome measures are due one year after the completion date **for that outcome.**

\* Primary Completion Date:

Month:  Day:  Year:  Type:

Final data collection date for primary outcome measure.

\* § Study Completion Date:

Month:  Day:  Year:  Type:

Final data collection date for study.

In the example above, Primary Outcome results are due by **September 01, 2024**. All study results must be entered by **December 01, 2024**. Some secondary results may be due earlier depending on data collection time frames for that outcome.

# Completion Dates Examples

Primary Outcome Measure:

1. Change in Pain as measured by the Visual Analogue Scale (VAS)  
[Time Frame: Baseline, 12 weeks]

Secondary Outcome Measures:

2. Change in the Beck Depression Inventory (BDI-II)  
[Time Frame: Baseline, 16 weeks]

The **Primary Completion Date** is when the last subject completes the VAS (i.e. the subject's 12 week visit).

The **Study Completion Date** is when the last subject completes the DBI-II (i.e. the last subject's 16 week visit)\*

\*If AE collection extends beyond 16 weeks then the study completion date would be the date of final AE collection.



# Sponsor/Collaborators

**\* Responsible Party:** Principal Investigator ▼

**For Responsible Party choose "Principal Investigator"**

**Investigator Information**

Investigator Name [Username]: Rachael Massey [rmassey] ▼  
Select the investigator's PRS account.  
The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.  
[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title: HRPP Research Compliance Specialist

Investigator Affiliation: University Hospital Cleveland Medical Center

**\* Sponsor:** University Hospitals Cleveland Medical Center  
Primary organization conducting study and associated data analysis (not necessarily a funding source).

**Should pre-populate as UH Cleveland Medical Center**

**Collaborators:** National Institutes of Health [x Delete]

**+ Add Collaborator**

Organization(s) providing support: funding, design, implementation, data analysis or reporting.  
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)  
Enter **only the organization name**.

**If the study is NIH funded, include the NIH office here**

Edit Oversight

Refer to definitions and ACT Checklist for help with this section

[Help](#) [Definitions](#)

\* § U.S. FDA-regulated Drug:

Yes

Studying one or more U.S. FDA-regulated drug or biologic products?

For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist \(PDF\)](#).

\* § U.S. FDA-regulated Device:

No

Studying one or more U.S. FDA-regulated device products?

For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist \(PDF\)](#).

\* U.S. FDA IND/IDE:

No

(Not public)

Studying drug/device p

(IND) Application or Investigational Device Exemption (IDE)?

If this is marked "Yes" the IND/IDE information is required

[\*] Product Exported from U.S.:

--Select--

Studying a drug or device product that is manufactured in and exported from the U.S.?

Human Subjects Protection Review:

Board Status: --Select--

Template language on next slide

Data Monitoring Committee:

Yes

FDA Regulated Intervention:

Yes

Section 801 = Applicable Clinical Trial

Section 801 Clinical Trial:

Yes

\* Human Subjects Protection Review:

Board Status: Submitted, approved ▼

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]

Approval Number: Approved IRB#

Board Name: University Hospitals Cleveland Medical Center IRB

Board Affiliation: University Hospitals Cleveland Medical Center

Board Contact: Phone: (216)844-1529 Extension:

Email: UHIRB@UHhospitals.org

Address: 11100 Euclid Avenue  
Cleveland, OH 4416

Enter these fields as shown

**TIP:** Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “subjects”

[Help](#) [Definitions](#)

\* Brief Summary: The purpose of this study is to assess the safety and efficacy of Remuverol on treatment of Condition A.

Describe the study in terms understandable to the lay public. **TIP:** Consider using the consent form since this is already written in lay terms

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

This field is optional and can be left blank. **Do not** include the entire protocol.

# Conditions

**Edit Conditions**

[Help](#) [Definitions](#)

**\* Conditions or Focus of Study:** Disk, Herniated × Delete

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.

**+ Add Condition**

Keywords: **+ Add Keyword**

**Overall condition/disease the study is focused on**

**Keywords help users find studies in the database**

**TIP:** Can only have one condition/key word per line. For multiple conditions/keywords hit "Add" button for each new entry.

[Help](#) [Definitions](#)

\* Study Type: Interventional

\* § Primary Purpose: Treatment

\* Study Phase: Phase 3  
Use "N/A" for trials that do not involve drug or biologic products.

\* § Interventional Study Model: Parallel

Model Description:

\* § Number of Arms: 2

\* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor
- None (Open Label)  
Check all roles that are masked or check None (Open Label).

Masking Description:

\* § Allocation: Randomized  
Select N/A for single-arm studies.

\* § Enrollment: Number of Participants: 75 Type: Anticipated

Use the definitions link to view definition of "enrolled"

Number enrolled should be changed to actual when a study has completed data collection.

[Help](#) [Definitions](#)

Arms:

\* Arm Title:

Formerly Arm Label:

\* Arm Type:

[\*] Arm Description:

Describe the intervention(s) to be administered.  
For drugs use generic name and include dosage form, dosage, frequency and duration.

---

\* Arm Title:

\* Arm Type:

[\*] Arm Description:

For Arm Type you must choose from drop down. Use definitions link for more info

Use to add additional arms

Arm description needs to describe intervention administered. This is not a required filed, but it is best to include for clarity.

[Help](#) [Definitions](#)

Arms: Experimental: Remuverol  
No Intervention: Placebo

Interventions:

\* Intervention Type:

\* Intervention Name:

For a drug, use generic name if established.  
Use the same name as in the associated Arm/Group Description(s).

[\*] Other Intervention Names:   
(if any)

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

\* § Intervention Description:

Do not repeat information already included in arm/group descriptions.

**NOTE:** Intervention Other Names have not been specified

\* Intervention Type:

\* Intervention Name:

[\*] Other Intervention Names:   
(if any)

\* § Intervention Description:

**TIP:** Record should include ALL interventions pre-specified in the protocol, even if it is not a intervention "of interest"

Placebo should be listed as a Drug intervention

Add each intervention administered separately



[Edit](#)

### Cross-Reference

Arms	Interventions	
	Drug: Remuverol	Drug: Placebo
Experimental: Remuverol	✓	
Placebo Comparator: Placebo		✓

✓ - Intervention is administered to patients in this Arm.

Each intervention has to be assigned to an arm. Hit **edit** here to do that.

\* Cross-Reference:

Arms	Interventions	
	Drug: Remuverol	Drug: Placebo
Experimental: Remuverol	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Placebo Comparator: Placebo	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Check boxes for Interventions associated with each Arm in the study.

# Outcome Measure: Tips

- Protocol/statistical analysis plan must be submitted with results and will be made public. There are some redactions that are allowed, but are limited. This is required for all results submissions, even voluntary submissions.
- Must include **ALL Primary and Secondary** outcomes listed in protocol (tertiary/exploratory are optional)
- Label outcomes as “primary” or “secondary” in the record the same as they are labeled in the protocol
  - May have more than one primary outcome if needed

## Outcome Measure: Title

### Title should include what you are measuring and how

- Include the metric (ie. scale, score, number, percentage)
  - Ex: Pain as measured by the Visual Analogue Scale
  - Ex: Number of AEs as measured by patient report
- Be clear and concise, no verbs
  - Ex: “Maximum tolerated dose of Drug A” is preferable over “To determine the maximum tolerated dose of Drug A in patients with breast cancer”. Only include what is being measured and how in the title.
- Only one measure per outcome
  - Ex: All-cause mortality, hospitalizations, and ER visits should be 3 separate outcomes
    - \*Exception-** if you are measuring a composite score, but must explain how you are measuring
      - Ex: Composite score of all-cause mortality, hospitalizations, and ER visits. In the description make sure to explain how you will combine all measures to get one overall raw score.

## Outcome Measure: Time Frame

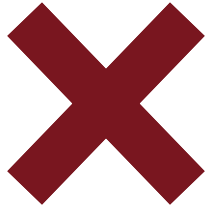
### Time Frame should include specific time point data was collected

- Specific time point of data collection for that outcome measure (e.g. # of minutes, hours, weeks, months, years)
    - Ex: During hospitalization, approximately 5 days
    - Ex: End of study, up to 12 weeks
  - Should only have one time point in the time frame, unless you are measuring a change. If you are measuring a change must have “change” in the title
    - Ex: Change in pain score as measured by the VAS, Time Frame: Baseline, 3 months, 6 months (Make sure to include all time points you are measuring the change)
- \*NOTE\*** If you are not measuring a change, each time point would be its own outcome measure
- Pain as measured by the VAS, Time Frame: Baseline
  - Pain as measured by the VAS, Time Frame: 3 months
  - Pain as measured by the VAS, Time Frame: 6 months

# Outcome Measure: Description

- Make sure to include the range and meaning of any scores used in a scale
  - Ex: The Visual Analog Scale is a 10 item questionnaire ranking the severity of pain. Scores are measured on a 5 point likert scale, with 5 being extreme pain and 1 being no pain at all.
- Descriptions are not required, but should be used to clarify what is measured and how

# Outcome Measure: Example



Title:	To determine the effect of Remuverol on pain in adults
Description:	
Time Frame:	Baseline, 12 weeks



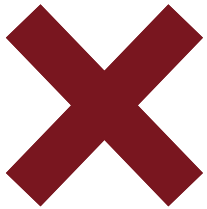
Title:	Change in pain as measured by the Visual Analogue Scale (VAS)
Description:	The Visual Analog Scale is a 10 item questionnaire ranking the severity of pain. Scores are measured on a 5 point likert scale, with 5 being extreme pain and 1 being no pain at all.
Time Frame:	Baseline, 12 weeks

There are multiple time points, so “change” is included in the title

The Title includes the scale that is used to asses the change in pain

The Description includes what the scale means and the range

# Outcome Measures: Example



Title:	To assess the safety of Remuverol
Description:	
Time Frame:	End of study



Title:	Number of participants with at least one adverse event as measured by patient report
Description:	Adverse events will include any AE related to study drug.
Time Frame:	End of study, up to 24 weeks

They will not just accept “safety”, they want to know how you are measuring safety.

“End of study” is not descriptive enough, need to add actual length of time

Since no change is being measured only one time point is needed

# Eligibility

**Required**

\* Sex: All   
Biological sex of eligible participants.

[\*] Gender Based: No   
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

\* Age Limits: Minimum: 18  Years  Maximum: N/A (No limit)

\* § Accepts Healthy Volunteers: No

\* Eligibility Criteria:

Inclusion Criteria:  
-

Exclusion Criteria:  
-|

Make sure to put a – before each inclusion/ Exclusion Criteria so it formats correctly

[Special Characters](#)



# Contacts/Locations

Name, phone number, and email are required

\* Central Contact Person:

First Name:  MI:  Last Name:  Degree:

Phone:  Ext:  Email:

Either Central Contact or Facility Contacts are required.  
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Central Contact Backup:

First Name:  MI:  Last Name:

Phone:  Ext:  Email:

Not required, but if you want to add someone- must include name, phone number and email

Overall Study Officials:

First Name:  MI:  Last Name:  Degree:

Organizational Affiliation:

Official's Role:

Must include PI listed with IRB, can add other Co-Is here as well

# IPD Sharing Statement

This is sharing individual participant level data, not aggregate data sets. If you plan to share this level of data you must present your plan and have it IRB approved.

ICMJE requires this question be answered, so do not leave as “Undecided”. Either mark “Yes” if you have already submitted and had your plan approved, or “No” if you have not yet submitted the plan to IRB.

If you mark “Yes” the following information is required:

- Must check all information that will be shared: Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR), Analytic Code
- Must provide a time frame which should include how the data will become available and for how long
- Must provide Access Criteria

# References

▼ Citations:

Links:

Available IPD/Information:

Here you made include any citations or links.

**NOTE:** CT.gov does not like the use of foot notes in the record.